



# ECSI

***"Your Regulatory Compliance Expert"***

May 29, 2019

Mr. Ezekiel Rodriguez  
Facilities Department  
ABBOTT VASCULAR  
26531 Ynez Road  
Temecula, California 92591

Subject: **RESULTS OF ANNUAL ETHYLENE OXIDE SOURCE TESTING AND LEAK TESTING PERFORMED AT ABBOTT VASCULAR IN TEMECULA, CALIFORNIA**

Dear Mr. Rodriguez:

Please find attached a presentation of the results of the ethylene oxide source testing and leak testing performed at your facility by ECSI, on Wednesday, May 29, 2019. These test results are to be kept with all records pertaining to SCAQMD-required testing of the EtO gas-sterilization system, and are to be made available upon request by the SCAQMD. A copy of all raw test data, complete with sample chromatograms and calibration data, will be maintained in our files, and will be made available upon request.

The test results indicate that you continue to operate your EtO sterilization and emission-control system (SCAQMD Permit Numbers F83295 and F83299) in compliance with SCAQMD Rule 1405. I will follow up with you in approximately five months to let you know when your next semi-annual leak test is due, and in approximately eleven months to let you know when your next annual source test/leak test is due.

The annual ethylene oxide emissions reported in Table 2 can be used for your facility's annual SCAQMD emissions report. If you have any questions or comments regarding this submittal, please contact me at (949)400-9145. We thank you for the opportunity to serve your needs.

Respectfully Submitted:

Daniel P. Kremer  
ECSI

**TABLE 1**  
**ETHYLENE OXIDE CONTROL EFFICIENCY**  
**OF AN ETHYLENE OXIDE EMISSION CONTROL DEVICE (ABATOR #2 - F83299)**  
**OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS**  
**IN TEMECULA, CALIFORNIA**  
**ON MAY 29, 2019**

<b><u>CYCLE</u></b> <b><u>PHASE</u></b>	<b><u>INJECTION</u></b> <b><u>TIME</u></b>	<b><u>INLET ETO</u></b> <b><u>CONC. (PPM)(1)</u></b>	<b><u>OUTLET ETO</u></b> <b><u>CONC. (PPM)(2)</u></b>	<b><u>ETO CONTROL</u></b> <b><u>EFFICIENCY</u></b>
Exhaust(3)	1229	6390	1.59	99.9751
Exhaust	1231	5860	0.01	99.9998
Exhaust	1233	4850	0.01	99.9998
Exhaust	1235	3760	0.01	99.9997
Exhaust	1237	122	0.01	99.9918
Exhaust	1239	<u>12.3</u>	<u>0.01</u>	<u>99.9187</u>
<b>TIME-WEIGHTED AVERAGE:</b>		<b>3499</b>	<b>0.2733</b>	<b>99.9808</b>
<b>SCAQMD REQUIRED CONTROL EFFICIENCY:</b>				<b>99.0</b>

Notes:

- (1) - PPM = parts per million by volume
- (2) - 0.01 ppm is the quantification limit for the detector used at the outlet.
- (3) - The exhaust phase started at 12:27, ended at 12:40.

**TABLE 2**  
**ETHYLENE OXIDE MASS EMISSIONS**  
**FROM A GAS STERILIZATION AND EMISSION CONTROL SYSTEM (F83299/F83295)**  
**OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS**  
**IN TEMECULA, CALIFORNIA**  
**ON MAY 29, 2019**

<b><u>CYCLE PHASE</u></b>	<b><u>STACK FLOW(1)</u></b>	<b><u>OUTLET ETO MASS FLOW(2)</u></b>	<b><u>MINUTES/ CYCLE</u></b>	<b><u>CYCLES/ YEAR</u></b>	<b><u>ANNUAL ETO MASS EMISSIONS(3)</u></b>
Exhaust	47.6 DSCFM	0.00000013 lbs/min	13	60	0.0038 lbs/year
<b>TOTAL ANNUAL ETO MASS EMISSIONS</b>					<b>0.0038 lbs/year</b>

Notes:

(1) - DSCFM = Dry Standard Cubic Feet per Minute

(2) - lbs/min = pounds per minute

(3) - lbs/year = pounds per year

**TABLE 3**  
**ETHYLENE OXIDE LEAK TESTING**  
**OF A GAS STERILIZATION SYSTEM (F83295)**  
**OPERATED BY ABBOTT CARDIOVASCULAR SYSTEMS**  
**IN TEMECULA, CALIFORNIA**  
**ON MAY 29, 2019**

<u>COMPONENT GROUP TESTED</u>	<u>LEAKING COMPONENTS FOUND</u>	<u>CONCENTRATION</u>
Gas Cartridge / Injector	None	<1.0 ppm (1)
Sterilizer Inlet / Inbleed Valve	None	<1.0 ppm
Door Seal	None	<1.0 ppm
Sterilizer Outlet / Chamber Drain	None	<1.0 ppm
Venturi System / Filter	None	<1.0 ppm
Emission Control Device Inlet	None	<1.0 ppm

Notes:

(1) - PPM = parts per million by volume

<u>DeltaP</u>	<u>SqRtDeltaP</u>	<u>Temp (F)</u>	<u>ppm EtO</u>		<u>stack ID =</u>	3	in.
					<u>stack area =</u>	0.049	sq. in.
					<u>press =</u>	28.65	in. Hg
					<u>Tstd =</u>	528	deg R
					<u>Pstd =</u>	29.92	in Hg
					<u>Cp =</u>	0.99	
					<u>Kp =</u>	85.49	
					<u>Velocity =</u>	29.27	ft/sec
					<u>Flow =</u>	47.6	dscfm
					<u>MWeto =</u>	44.05	
					<u>MolVol =</u>	385.32	
					<u>ppmv/ft3 =</u>	1000000	
Average =							
0.1100	0.3317	428	0.2357				
	=	888	degR		<u>EtO Mass Flow (Exh) =</u>	0.0000013	lbs/min
					<u>min/cycle =</u>	50	
					<u>cycles/year =</u>	60	
					<u>Annual EtO Emissions =</u>	0.0038	lbs/year